

## 510(k) Summary

K060030

1. Owner Information: BioBarrier, Inc.  
12104 Bonny Lane  
Los Angeles, CA 90049  
Phone: 310-472-7170
2. Contact: David W. Mullis, Jr., Ph.D., RAC  
Telephone: 779-207-9174  
FAX: 770-207-7682
- Date: December 30, 2005
2. Trade Name: The Double™ Glove  
Common Name: Surgical Glove  
Classification: Surgeon's Glove 21CFR878.4461  
Code: 79KGO
3. Predicate Device: -Class I Surgeon's Gloves, Powder-free  
-Meets all ASTM D 3577 requirements  
-Predicate: K033564, Kanam Latex Industries Powder-free Latex Surgeon's Gloves Polymer Coated Sterile Contains 50 micrograms or less of total water extractable protein per gram
4. Device Description: The Double™ Glove, a Single-Donning™ Double Glove with 2 Discrete Layers Fused at the Wrist. A Class I, Powder-free, Polymer Coated, Latex Surgeon's Glove
5. Intended Use: The powderfree, polymer coated, sterile surgeon's glove is a disposable device made of natural rubber latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.
6. Technological Characteristics: The Double™ Glove characteristics are summarized below compared to ASTM requirements and to the predicate device.
- | <u>Characteristic</u>             | <u>Standard</u>           |
|-----------------------------------|---------------------------|
| Dimensions                        | Meets ASTM D 3577         |
| Physical Properties               | Meets ASTM D 3577, Type I |
| Freedom from Holes                | Meets ASTM D 3577         |
| Biocompatibility:                 |                           |
| Primary Skin Irritation (Rabbits) | Pass                      |
| Guinea Pig Sensitization          | Pass                      |
7. Performance Data: The performance data are the same as summarized in No. 6, above.
8. Clinical Data: Clinical data not required.
9. Conclusions: The Double™ Glove meets the technological characteristics of ASTM D 3577 and is substantially equivalent to the predicate device and Class I, powder-free, latex surgeon's gloves with a less than 50 microgram/gram of water extractable protein claim.

JUN 27 2006



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 27 2006

Biobarrier, Incorporated  
C/O Dr. David W. Mullis  
Mullis & Associates, Incorporated  
367 Pleasant Valley Road  
P.O. Box 39  
Good Hope, Georgia 30641

Re: K060030

Trade/Device Name: Powder-Free, Polymer Coated, Sterile, Single Donning Double  
Layer, Surgeon's Glove Contains 50 Micrograms or Less of total  
Water Extractable Protein Per Gram

Regulation Number: 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: I

Product Code: KGO

Dated: June 5, 2006

Received: June 6, 2006

Dear Dr. Mullis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

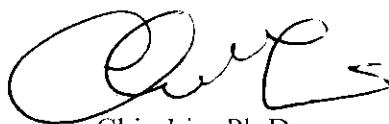
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K060030

Applicant: BioBarrier, Inc.

Device Name: Powder-free, polymer coated, sterile, single donning double layer, surgeon's glove contains 50 micrograms or less of total water extractable protein per gram.

Indications for Use: The powder-free, polymer coated, sterile surgeon's glove is a disposable device made of natural rubber latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

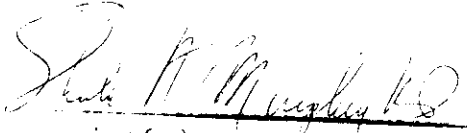
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Shanti K. Murphy, MD 4/27/04  
Chief of Anesthesiology, General Hospital,  
Drug Control, Dental Devices  
K060030